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Physical training in chronic concussion rehabilitation

Submission date
12/06/2025

Recruitment status
No longer recruiting

Registration date
18/06/2025

Overall study status
Completed

Last Edited
17/06/2025

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to investigate the effectiveness of a specialized training program in reducing persistent symptoms in individuals who have experienced a concussion. Many people with a concussion recover within weeks, but some continue to experience symptoms such as headaches, dizziness, fatigue, and difficulties with concentration for months or even years. This study examines whether a targeted training program, focusing on visual, vestibular (balance-related), and aerobic (exercise-based) rehabilitation, can help improve recovery and reduce symptoms.

Who can participate?
Adults aged 18 to 65 years who have experienced a concussion and continue to have persistent symptoms may be eligible to participate. Participants must meet specific inclusion criteria, such as having a concussion diagnosed by a medical professional and being willing to engage in the study's training program.

What does the study involve?
Participants will take part in an 8-week training program designed to address common concussion-related difficulties. This includes exercises targeting vision, balance, and physical endurance. The study is structured as a randomized controlled trial, meaning some participants will receive the training first, while others will receive an alternative intervention before switching groups. Participants will complete symptom assessments before, during, and after the program to evaluate progress.

What are the possible benefits and risks?
The potential benefits of participating include improvements in symptoms, balance, and overall well-being. The exercises are designed to be safe and are commonly used in concussion rehabilitation. However, some individuals may experience temporary discomfort, such as dizziness or fatigue, as they adjust to the training program. Study staff will closely monitor participants to ensure their safety.

Where is the study run from?
The study is being conducted at Cervello in Roskilde, Denmark, a rehabilitation center specializing in concussion recovery.

When is the study starting and how long will it run?
January 2023 to December 2024

Who is funding the study?
The study is funded by Offerfonden (Danish Victims Fund) and Cervello A/S.

Who is the main contact?
Dr Kenneth Jay, kja@cervello.dk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
FYTECH2023

Study information

Scientific Title
Targeting persistent symptoms in post-concussion syndrome: a randomized controlled cross-over trial of visual and vestibular training supercharged with aerobic exercise

Acronym
FYTECH

Study objectives
It is hypothesized that the intervention, combining visual and vestibular exercises supercharged with aerobic training, would lead to statistically significant improvements in RPSQ scores compared to a control condition involving guided mindfulness relaxation. Additionally, the researchers expected improvements in postural sway, as measured by the 95% confidence ellipse area (95% CEA) on a force plate, and in physical exertion capacity, measured as time to symptom exacerbation or volitional failure in a Buffalo Concussion Treadmill Test (BCTT). The researchers further posited that a multimodal intervention with combined visual, vestibular and aerobic training could yield sustained benefits, with participants receiving the training intervention first retaining those benefits during the control phase, reflecting potential long-term changes in symptom management and recovery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/02/2023, Scientific Ethics Commitee Region Zealand (Region Sjaelland, Data og Udviklingsstøtte, Alleen 15, Sorø, 4180, Denmark; +45 (0)24767199; rvk-sjaelland@regionsjaelland.dk), ref: SJ-987

Study design
Randomized controlled cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other therapist office

Study type(s)
Treatment

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Persistent post-concussion symptoms (PPCS)

Interventions
The present study, conducted between January 2023 and March 2024 at Cervello in Roskilde, Denmark, is a single-blind randomized controlled 2 x 2 cross over trial adhering to the CONSORT criteria of randomized controlled trials. The methods and materials section of this study provides a detailed roadmap of the interventional procedures, ensuring the study's validity and reproducibility.

The intervention was designed to address the diverse impairments commonly associated with concussion, with a focus on improving physical function, postural stability, and improving physical capacity. Postural sway analysis, physical capacity testing through the Buffalo Concussion Treadmill Test (BCTT), and symptom evaluation using the RPSQ, provided the baseline outcome measurements and a baseline assessment of each participant by the specialized neurophysiotherapist provided individual measures to guide the individualization and calibrating the intervention's intensity and complexity to match the participants' functional levels.

The active intervention aimed to enhance visual, vestibular, and aerobic function through structured group-based physical training and personalized home exercises. To promote adherence, participants were encouraged to maintain logbooks and attended bi-weekly virtual sessions/phone calls to receive individualized guidance and feedback.

In parallel, the control group (CG) participated in a relaxation-based intervention, which included guided mindfulness body scans narrated by a second neurophysiotherapist with extensive mindfulness relaxation teaching experience. This component emphasized daily mindfulness practice as a method of symptom management, with participants logging their relaxation activities to track adherence. This dual intervention design allowed for a rigorous comparison between the effects of targeted physical rehabilitation and non-physical mindfulness-based relaxation on post-concussion recovery.

Sample size calculation:
Previous unpublished observations from a similar population on the Rivermead Post Concussion Symptoms Questionnaire (RPSQ) suggests that the baseline mean RPSQ score for the Control Group (CG) 1 is approximately 37 points with a standard deviation (SD) of 8, while for the Training Group (TG), the baseline mean score is approximately 35 points with a standard deviation of 7. The anticipated intervention effects are as follows: the control intervention is expected to reduce RPSQ scores by approximately 6 points, representing around a 16% reduction, based on prior outcomes from this type of intervention. In contrast, the training intervention is expected to reduce RPSQ scores by approximately 10 points, which corresponds to around a 29% reduction. This anticipated effect is based on evidence of a higher impact reported in unpublished observations focused on symptom severity alleviation. The effect difference between the two interventions is projected to be 4 RPSQ points. A priori analysis suggests a pooled standard deviation of 5 for the difference in symptom scores between these two conditions. This leads to an expected effect size of 0.8, which is calculated as the difference in means (4 points) divided by the pooled standard deviation (5 points), indicating a moderate-to-large effect size. To detect a standardized effect size of 0.8, with a 5% significance level and 80% power, a sample size of 12 participants per group is required, yielding a total sample size of 24 participants. This sample size is sufficient to capture the anticipated differences between the interventions.

Randomization and blinding:
Participants are randomized in the order in which they are included in the study, having provided written informed consent and completed baseline testing. Randomization was carried out using a computer-generated randomization sequence within a block design of 6-8 participants. Each participant was assigned an identification number at the time of randomization. Baseline testing was conducted before randomization, ensuring that all parties remain blinded to the treatment allocation at this stage.

At the final testing stage, an external tester, who was blinded to the participants' treatment assignments, conducted the assessments. Naturally, the neurophysiotherapists delivering the interventions could not be blinded, and participants were aware of which treatment they were receiving. However, participants were explicitly informed that the researchers did not know which treatment was preferable, maintaining equipoise in the study's conduct.

Intervention Type
Behavioural

Primary outcome measure
Persistent post-concussion symptoms measured using the Rivermead Post Concussion Questionnaire at four timepoints:
1. Before randomisation into the two groups
2. After 8 weeks of intervention treatment/sham treatment (which is also the start of washout)
3. After the washout, which is after 4-6 weeks, which also marks the beginning of the cross-over intervention/sham treatment
4. After an additional 8 weeks at the conclusion of the intervention/sham treatment after crossover

Secondary outcome measures
1. Buffalo concussion treadmill test measured in minutes to cessation
2. Postural Sway (95% CEA) measured using a KINVENT DELTA forceplate and software

Measured at four timepoints:
1. Before randomisation into the two groups
2. After 8 weeks of intervention treatment/sham treatment (which is also the start of washout)
3. After the washout, which is after 4-6 weeks, which also marks the beginning of the cross-over intervention/sham treatment
4. After an additional 8 weeks at the conclusion of the intervention/sham treatment after crossover

Overall study start date
09/01/2023

Completion date
21/12/2024

Eligibility

Key inclusion criteria
1. Individuals who have sustained a concussion, defined in this study as resulting from a traumatic event involving a direct blow to the head, or a jolt capable of causing movement of the brain inside the skull, in conjunction with at least one of the following:
1.1. Brief loss of consciousness (up to 30 minutes)
1.2. Amnesia before or after the event (up to 24 hours post-trauma)
1.3. Altered consciousness during the trauma (such as confusion or disorientation)
1.4. Transient neurological symptoms, or
1.5. A Glasgow Coma Scale (GCS) score of no less than 13 at 30 minutes, which corresponds to a diagnosis of mild traumatic brain injury meeting the ICD-10 classification for concussion (S06.0X0A) within the last 3 months.

2. Participants must be between the ages of 18 and 65 years.
3. Participants must be motivated to engage in physical training and demonstrate a willingness to follow the exercise protocols.
4. They must be able to speak and understand Danish.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
40

Total final enrolment
25

Key exclusion criteria
1. GCS less than 13 at 30 minutes after injury
2. Individuals with severe psychiatric disorders.
3. Individuals with any pre-existing physical or psychological disability or other conditions that would prevent participation in physical training.
4. Those experiencing severe vestibular (balance) or oculomotor (vision) difficulties that would inhibit their ability to train due to conditions other than concussion/mTBI (e.g., cancer, poisoning, infectious diseases).
5. Pregnant women.
6. Individuals currently using prescription medications that could interfere with visual and vestibular function.
7. Participants with blood pressure readings above 160/100.
8. Participants were permitted to continue with necessary specialized treatments, such as manual therapy for neck-related issues, during the study period. However, they were not allowed to engage in additional physical training outside the study protocol. If any participant began other specialized physical treatments or exercises during the project period, they were excluded from the study.

Date of first enrolment
07/02/2023

Date of final enrolment
01/06/2024

Locations

Countries of recruitment
Denmark

Study participating centre
Cervello
Langebjerg 1
Roskilde
Denmark
4000

Sponsor information

Organisation
Offerfonden

Sponsor details
Danish Department of Justice, Civilstyrelsen, Offerfonden
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Sponsor type
Government

Website
https://www.civilstyrelsen.dk/sagsomraader/raadet-for-offerfonden/om-offerfonden

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cervello A/S

Results and Publications

Publication and dissemination plan
Publication in MEDICINE within the next few months as the first choice of journal

Intention to publish date
01/09/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Kenneth Jay (kja@cervello.dk)

IPD sharing plan summary
Available on request